

Sheet 1 of 4

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| APPLICANT FACSIMILE OF FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE | | ATTY DOCKET NO. UMV-1184CPCN | SERIAL NO. 09/819098 |
| LIST OF PUBLICATIONS CITED BY APPLICANT (Use several sheets if necessary) | | APPLICANT Kaufman, R. J. et al. | |
| FILING DATE April 11, 2001 | | GROUP 1653 | |

U.S. PATENT DOCUMENTS

| EXAMINER INITIAL | | DOCUMENT NUMBER | DATE | NAME | CLASS | SUBCLASS | FILING DATE IF APPROPRIATE |
|---------------------|----|-----------------|-------|-------------------|-------|----------|-------------------------------|
| <i>[initials]</i> | A1 | 4,757,006 | 07/88 | Toole, Jr. et al. | 435 | 68 | |
| <i>[initials]</i> | A2 | 4,868,112 | 09/89 | Toole, Jr. | 435 | 68 | |
| <i>[initials]</i> | A3 | 5,004,803 | 04/91 | Kaufman et al. | 530 | 383 | |
| <i>[initials]</i> | A4 | 5,045,455 | 09/91 | Kuo et al. | 435 | 69.6 | |
| <i>[initials]</i> | A5 | 5,214,033 | 05/93 | Zimmerman et al. | 517 | 21 | |
| <i>[initials]</i> | A6 | 5,250,421 | 10/93 | Kaufman et al. | 435 | 69.6 | |
| <i>[initials]</i> | A7 | 5,451,521 | 09/95 | Kaufman et al. | 435 | 240.2 | |
| <i>[initials]</i> | A8 | 5,563,045 | 10/96 | Pittman et al. | 435 | 69.6 | |
| <i>[initials]</i> | A9 | 5,661,008 | 08/97 | Almstedt et al. | 435 | 69.6 | |

FOREIGN PATENT DOCUMENTS


| | | DOCUMENT NUMBER | DATE | COUNTRY | CLASS | SUBCLASS | TRANSLATION | |
|-------------------|-----|-----------------|-------|---------|-------|----------|-------------|----|
| | | | | | | | YES | NO |
| <i>[initials]</i> | A10 | WO 87/04187 | 07/87 | WO | | | | |
| <i>[initials]</i> | A11 | WO 87/06101 | 10/87 | WO | | | | |
| <i>[initials]</i> | A12 | WO 87/07144 | 12/87 | WO | | | | |
| <i>[initials]</i> | A13 | WO 88/03558 | 05/88 | WO | | | | |
| <i>[initials]</i> | A14 | WO 88/08035 | 10/88 | WO | | | | |
| <i>[initials]</i> | A15 | EP 295597 | 12/88 | EPO | | | | |
| <i>[initials]</i> | A16 | WO 91/07490 | 05/91 | WO | | | | |
| <i>[initials]</i> | A17 | EP 197901 | 07/91 | EPO | | | | |
| <i>[initials]</i> | A18 | WO 97/03194 | 01/97 | WO | | | | |
| <i>[initials]</i> | A19 | WO 97/03195 | 01/97 | WO | | | | |
| <i>[initials]</i> | A20 | WO 97/40145 A1 | 10/97 | WO | | | | |

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| <i>[initials]</i> | A21 | Bertina et al. "Mutation in blood coagulation factor V associated with resistance to activated protein C." <i>Nature</i> . 1994 May 5;369(6475):64-7 |
| <i>[initials]</i> | A22 | Blond-Elguindi et al. "Affinity panning of a library of peptides displayed on bacteriophages reveals the binding specificity of BiP." <i>Cell</i> . 1993 Nov 19;75(4):717-28 |
| <i>[initials]</i> | A23 | Brinkhous et al. "Purified human factor VIII procoagulant protein: comparative hemostatic response after infusions into hemophilic and von Willebrand disease dogs." <i>PNAS USA</i> . 1985 Dec;82(24):8752-6 |
| <i>[initials]</i> | A24 | Castaman et al. "Effectiveness of high-dose intravenous immunoglobulin in a case of acquired von Willebrand syndrome with chronic melena not responsive to desmopressin and factor VIII concentrate." <i>Am. J. Hematol</i> . 1992 Oct;41(2):132-6 |
| Examiner <i>[Signature]</i> | | Date Considered 8/16/04 |
| *EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. | | |


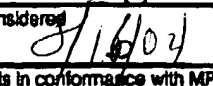
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| APPLICANT FACSIMILE OF FORM PTO-1449 REV 7-89 | U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE | ATTY DOCKET NO. UMV-1184CPCN | Sheet 2 of 4 SERIAL NO. 09/819098 |
| LIST OF PUBLICATIONS CITED BY APPLICANT (Use several sheets if necessary) | | APPLICANT Kaufman, R. J. et al. FILING DATE April 11, 2001 GROUP 1653 | |

OTHERS (including Author, Title, Date, Pertinent Pages, Etc.)

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| A | B1 | Cripe et al. "Structure of the gene for human coagulation factor V." <i>Biochemistry</i> . 1992 Apr 21;31(15):3777-85 |
| B | B2 | Dahlbäck et al. "Familial thrombophilia due to a previously unrecognized mechanism characterized by poor anticoagulant response to activated protein C: prediction of a cofactor to activated protein C." <i>PNAS USA</i> 1993 Feb 1;90(3):1004-8 |
| A | B3 | Dahlbäck et al. "Inherited resistance to activated protein C is corrected by anticoagulant cofactor activity found to be a property of factor V." <i>PNAS USA</i> 1994 Feb 15;91(4):1396-400 |
| A | B4 | Davie et al. "The coagulation cascade: initiation, maintenance, and regulation." <i>Biochemistry</i> . 1991 Oct 29;30(43):10363-70 |
| A | B5 | Dorner et al. "The relationship of N-linked glycosylation and heavy chain-binding protein association with the secretion of glycoproteins." <i>J. Cell Biol.</i> 1987 Dec;105(6 Pt 1):2665-74 |
| A | B6 | Dorner et al. "Increased synthesis of secreted proteins induces expression of glucose-regulated proteins in butyrate-treated Chinese hamster ovary cells." <i>J. Biol. Chem.</i> 1989;264(34):20602-7 |
| A | B7 | Dorner et al. "Protein dissociation from GRP78 and secretion are blocked by depletion of cellular ATP levels." <i>PNAS USA</i> 1990 Oct;87(19):7429-32 |
| A | B8 | Dorner et al. "Overexpression of GRP78 mitigates stress induction of glucose regulated proteins and blocks secretion of selective proteins in Chinese hamster ovary cells." <i>EMBO J.</i> 1992 Apr;11(4):1563-71 |
| A | B9 | Eaton et al. "Proteolytic processing of human factor VIII. Correlation of specific cleavages by thrombin, factor Xa, and activated protein C with activation and inactivation of factor VIII coagulant activity." <i>Biochemistry</i> . 1986 Jan 28;25(2):505-12 |
| A | B10 | Fay et al. "von Willebrand factor mediates protection of factor VIII from activated protein C-catalyzed inactivation." <i>J. Biol. Chem.</i> 1991 Feb 5;266(4):2172-7 |
| A | B11 | Fay et al. "Human factor VIIIa subunit structure. Reconstruction of factor VIIIa from the isolated A1/A3-C1-C2 dimer and A2 subunit." <i>J. Biol. Chem.</i> 1991 May 15;266(14):8957-62 |
| A | B12 | Fay et al. "Activated protein C-catalyzed inactivation of human factor VIII and factor VIIIa. Identification of cleavage sites and correlation of proteolysis with cofactor activity." <i>J. Biol. Chem.</i> 1991 Oct 25;266(30):20139-45 |
| A | B13 | Fay et al. "Role of the COOH-terminal acidic region of A1 subunit in A2 subunit retention in human factor VIIIa." <i>J. Biol. Chem.</i> 1993 Aug 25;268(24):17861-6 |
| A | B14 | Fay et al. "Factor VIIIa A2 subunit residues 558-585 represent a factor IXa interactive site." <i>J. Biol. Chem.</i> 1994 Aug 12;269(32):20522-7 |
| A | B15 | Flynn et al. "Peptide binding and release by proteins implicated as catalysts of protein assembly." <i>Science</i> 1989 Jul 28;245(4916):385-90 |
| A | B16 | Fulcher et al. "Proteolytic inactivation of human factor VIII procoagulant protein by activated human protein C and its analogy with factor V." <i>Blood</i> 1984 Feb;63(2):486-9 |
| A | B17 | Glitschler et al. "Characterization of the human factor VIII gene." <i>Nature</i> 1984 Nov 22-28;312(5992):326-30 |
| A | B18 | Guinto et al. "The complete cDNA sequence of bovine coagulation factor V." <i>J. Biol. Chem.</i> 1992 Feb 15;267(5):2971-8 |
| A | B19 | Healey et al. "Residues Glu2181-Val2243 Contain a Major Determinant of the Inhibitory Epitope in the C2 Domain of Human Factor VIII." <i>Blood</i> , 1998, 92(10):3701-9 |
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| APPLICANT FACSIMILE OF FORM PTO-1409 REV 7-80 | U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE | ATTY DOCKET NO UMV-1184CPCN | SERIAL NO. 09/819098 |
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| | | GROUP 1653 | |

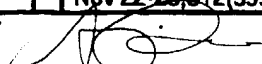
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| A9 | C1 Jenny et al. "Complete cDNA and derived amino acid sequence of human factor V." <i>PNAS USA</i> 1987 Jul;84(14):4846-50 |
| A10 | C2 Kane et al. "Cloning of a cDNA coding for human factor V, a blood coagulation factor homologous to factor VIII and ceruloplasmin." <i>PNAS USA</i> 1986 Sep;83(18):6800-4 |
| A10 | C3 Kaufman et al. "Amplification and expression of sequences cotransfected with a modular dihydrofolate reductase complementary DNA gene." <i>J. Mol. Biol.</i> 1982 Aug 25;159(4):601-21 |
| A10 | C4 Kaufman et al. "Identification of the components necessary for adenovirus translational control and their utilization in cDNA expression vectors." <i>PNAS USA</i> 1985 Feb;82(3):689-93 |
| A10 | C5 Kaufman et al. "Synthesis, processing, and secretion of recombinant human factor VIII expressed in mammalian cells." <i>J. Biol. Chem.</i> 1988 May 5;263(13):6352-62 |
| A10 | C6 Kozutsumi et al. "The presence of malformed proteins in the endoplasmic reticulum signals the induction of glucose-regulated proteins." <i>Nature</i> 1988 Mar 31;332(6163):462-4 |
| A10 | C7 Koedam et al. "Inactivation of human factor VIII by activated protein C. Cofactor activity of protein S and protective effect of von Willebrand factor." <i>J. Clin. Invest.</i> 1988 Oct;82(4):1238-43 |
| A10 | C8 Lenting et al. "Identification of a binding site for blood coagulation factor IXa on the light chain of human factor VIII." <i>J. Biol. Chem.</i> 1994 Mar 11;269(10):7150-5 |
| A10 | C9 Layte et al. "Sulfation of Tyr1680 of human blood coagulation factor VIII is essential for the interaction of factor VIII with von Willebrand factor." <i>J. Biol. Chem.</i> 1991 Jan 15;266(2):740-6 |
| A10 | C10 Lollar et al. "Structural basis for the decreased procoagulant activity of human factor VIII compared to the porcine homolog." <i>J. Biol. Chem.</i> 1991 Jul 5;266(19):12481-6 |
| A10 | C11 Lusky et al. "Characterization of the bovine papilloma virus plasmid maintenance sequences." <i>Cell.</i> 1984 Feb;36(2):391-401 |
| A10 | C12 Mann et al. "Cofactor proteins in the assembly and expression of blood clotting enzyme complexes." <i>Annu. Rev. Biochem.</i> 1988;57:915-56 |
| A10 | C13 Marquette et al. "A 110-amino acid region within the A1-domain of coagulation factor VIII inhibits secretion from mammalian cells." <i>J. Biol. Chem.</i> 1995 Apr 28;270(17):10297-303 |
| A10 | C14 Michnick et al. "Identification of individual tyrosine sulfation sites within factor VIII required for optimal activity and efficient thrombin cleavage." <i>J. Biol. Chem.</i> 1994 Aug 5;269(31):20095-102 |
| A10 | C15 Munro et al. "An Hsp70-like protein in the ER: identity with the 78 kd glucose-regulated protein and immunoglobulin heavy chain binding protein." <i>Cell.</i> 1986 Jul 18;46(2):291-300 |
| A10 | C16 Nesheim et al. "The effect of plasma von Willebrand factor on the binding of human factor VIII to thrombin-activated human platelets." <i>J. Biol. Chem.</i> 1991 Sep 25;266(27):17815-20 |
| A10 | C17 Ortel et al. "Structural model of human ceruloplasmin based on internal triplication, hydrophilic/hydrophobic character, and secondary structure of domains." <i>PNAS USA</i> 1984 Aug;81(15):4761-5 |
| A10 | C18 Pipe et al., "Construction and characterization of inactivation resistant factor VIII," <i>Blood</i> , 88(10):441 (1996) |
| A10 | C19 Pipe et al., "Characterization of a genetically engineered inactivation-resistant coagulation factor VIIIa." <i>PNAS USA</i> . 1997 Oct 28;94(22):11851-6 |
| A10 | C20 Pittman et al., "Proteolytic requirements for thrombin activation of anti-hemophilic factor (factor VIII)," <i>Proc. Nat. Acad. Sc.</i> 85:2429-33 (1988) |
| A10 | C21 Pittman et al. "A2 domain of human recombinant-derived factor VIII is required for procoagulant activity but not for thrombin cleavage." <i>Blood</i> . 1992 Jan 15;79(2):389-97 |
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| APPLICANT FACSIMILE OF FORM PTO-1448 REV 7-88 | U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE | ATTY DOCKET NO. UMV-1184CPCN | SERIAL NO. 09/819098 |
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| D1 | Pittman <i>et al.</i> "Post-translational requirements for functional factor V and factor VIII secretion in mammalian cells." <i>J. Biol. Chem.</i> 1994 Jun 24;269(25):17329-37 |
| D2 | Pittman <i>et al.</i> "Role of the B domain for factor VIII and factor V expression and function." <i>Blood.</i> 1994 Dec 15;84(12):4214-25 |
| D3 | Saenko <i>et al.</i> "A novel mechanism for inhibition of factor VIII activity by an antibody with a C2 domain epitope, residues 2248-2285." <i>Blood</i> 1995;86 Abstr. 749 |
| D4 | Scandella <i>et al.</i> "Some factor VIII inhibitor antibodies recognize a common epitope corresponding to C2 domain amino acids 2248 through 2312, which overlap a phospholipid-binding site." <i>Blood.</i> 1995 Sep 1;86(5):1811-9 |
| D5 | Shima <i>et al.</i> "Common inhibitory effects of human anti-C2 domain inhibitor alloantibodies on factor VIII binding to von Willebrand factor." <i>Blood.</i> 1995;86 Abstr. 748 |
| D6 | Shima <i>et al.</i> "Common inhibitory effects of human anti-C2 domain inhibitor alloantibodies on factor VIII binding to von Willebrand factor." <i>Br. J. Haematol.</i> 1995 Nov;91(3):714-21 |
| D7 | Stubbs <i>et al.</i> "cDNA cloning of a mouse mammary epithelial cell surface protein reveals the existence of epidermal growth factor-like domains linked to factor VIII-like sequences." <i>PNAS USA</i> 1990 Nov;87(21):8417-21 |
| D8 | Sun <i>et al.</i> "Blood coagulation factor Va abnormality associated with resistance to activated protein C in venous thrombophilia." <i>Blood.</i> 1994 Jun 1;83(11):3120-5 |
| D9 | Svensson <i>et al.</i> "Resistance to activated protein C as a basis for venous thrombosis." <i>N. Engl. J. Med.</i> 1994 Feb 24;330(8):517-22 |
| D10 | Swaroop, M. et al., "Mutation of Phe309Ser, a putative BIP binding site, enhances secretion of coagulation factor VIII." <i>Blood</i> , 88(10):441a (1996) |
| D11 | Takahashi <i>et al.</i> "Single-chain structure of human ceruloplasmin: the complete amino acid sequence of the whole molecule." <i>PNAS USA.</i> 1984 Jan;81(2):390-4 |
| D12 | Toole <i>et al.</i> "Molecular cloning of a cDNA encoding human antihemophilic factor." <i>Nature.</i> 1984 Nov 22-28;312(5992):342-7 |
| D13 | Toole <i>et al.</i> "A large region (approximately equal to 95 kDa) of human factor VIII is dispensable for in vitro procoagulant activity." <i>PNAS USA</i> 1986 Aug;83(16):5939-42 |
| D14 | Toole, J. J. et al., "Exploration of structure-function relationships in human factor VIII by site-directed mutagenesis." <i>Cold Spring Harbor Symposia on Quantitative Biology</i> , 51(1):543-9 (1986) |
| D15 | Varadi <i>et al.</i> "Influence of factor V and factor Va on APC-induced cleavage of human factor VIII." <i>Thromb. Haemost.</i> 1995 Apr;73(4):730-1 |
| D16 | Varadi <i>et al.</i> "A chromogenic assay for activated protein C resistance." <i>Br. J. Haematol.</i> 1995 Aug;90(4):884-91 |
| D17 | Vehar <i>et al.</i> "Structure of human factor VIII." <i>Nature.</i> 1984 Nov 22-28;312(5992):337-42 |
| D18 | Walker <i>et al.</i> "Inactivation of factor VIII by activated protein C and protein S." <i>Arch. Biochem. Biophys.</i> 1987 Jan;252(1):322-8 |
| D19 | Walker <i>et al.</i> "Identification of the binding site for activated protein C on the light chain of factors V and VIII." <i>J. Biol. Chem.</i> 1990 Jan 25;265(3):1484-9 |
| D20 | Wood <i>et al.</i> "Expression of active human factor VIII from recombinant DNA clones." <i>Nature.</i> 1984 Nov 22-28;312(5992):330-7 |

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